# EXHIBIT 1

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Securities and Exchange Commission
Washington, D.C. 20549

# Form 10-K

Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2003

Commission file number 001-6351

# Eli Lilly and Company

An Indiana corporation

I.R.S. employer number 35-0470950

Address: Lilly Corporate Center, Indianapolis, Indiana 46285

Telephone number, including area code: (317) 276-2000

**Securities registered pursuant to Section 12(b) of the Act:**

| Title of Each Class | Name of Each Exchange On Which Registered |
|---|---|
| Common Stock | New York and Pacific Stock Exchanges |
| Preferred Stock Purchase Rights | New York and Pacific Stock Exchanges |
| 8-3/8% Notes Due December 1, 2006 | New York Stock Exchange |
| 6.57% Notes Due January 1, 2016 | New York Stock Exchange |
| 7-1/8% Notes Due June 1, 2025 | New York Stock Exchange |
| 6.77% Notes Due January 1, 2036 | New York Stock Exchange |

**Securities registered pursuant to Section 12(g) of the Act:** None

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months, and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in the definitive proxy statement incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

Indicate by check mark whether the Registrant is an accelerated filer as defined in Exchange Act Rule 12b-2. Yes ☒ No ☐

Aggregate market value of voting stock of the Registrant held by non-affiliates as of February 27, 2004 (Common Stock): approximately $71,971,900,000

Number of shares of common stock outstanding as of February 27, 2004: 1,128,884,423

Portions of the following documents have been incorporated by reference into this report:

| Registrant's Document | Parts Into Which Incorporated |
|---|---|

| | |
|---|---|
| Annual Report to Shareholders for fiscal year ended December 31, 2003 | Parts I, II, and IV |
| Proxy Statement dated March 12, 2004 | Part III |

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Puerto Rico. We also lease sales and administrative offices in Indianapolis and a number of other cities located in the United States and abroad.

We own production and distribution facilities in 13 countries outside the United States and Puerto Rico, containing an aggregate of approximately 4.4 million square feet of floor space. Major production sites include facilities in the United Kingdom, France, Ireland, Spain, Brazil, Italy, and Mexico. We lease production and warehouse facilities in Puerto Rico and several countries outside the United States.

Our research and development facilities in the United States consist of approximately 4.2 million square feet and are located primarily in Indianapolis and Greenfield, Indiana. Our major research and development facilities abroad are located in Belgium, United Kingdom, Germany, Canada, and Spain and contain an aggregate of approximately 650,000 square feet.

We believe that none of our properties is subject to any encumbrance, easement, or other restriction that would detract materially from its value or impair its use in the operation of the business. The buildings we own are of varying ages and in good condition.

**Item 3. Legal Proceedings**

**Zyprexa Patent Litigation**

Three generic pharmaceutical manufacturers, Zenith Goldline Pharmaceuticals, Inc. (Zenith), Dr. Reddy's Laboratories, Ltd. (Reddy) and Teva Pharmaceuticals (Teva) have submitted abbreviated new drug applications (ANDAs) seeking permission to market generic versions of Zyprexa in various dosage forms several years prior to the expiration of our U.S. patents for the product, alleging that our patents are invalid or not infringed. In April 2001, we filed suit against Zenith in the U.S. District Court for the Southern District of Indiana seeking a ruling that the challenges to our compound patent (expiring in 2011) are without merit. We filed similar suits in the same court against Reddy in June 2001 and Teva in September 2002. The cases have been consolidated. A trial before a district court judge in Indianapolis was held in January and February of 2004 and the parties are now in the process of submitting post-trial briefs. A ruling from the trial court is expected in the second or third quarter of 2004. Regardless of the trial court's ruling, we anticipate that appeals will follow. If we are unsuccessful at the trial court level, we cannot predict whether any of the generic companies would launch generic versions of Zyprexa prior to a final resolution of any appeals.

We believe that the generic manufacturers' claims are without merit and we expect to prevail in this litigation. However, it is not possible to predict or determine the outcome of this litigation and, accordingly, we can provide no assurance that we will prevail. An unfavorable outcome would have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

**Other Patent Litigation**

In October 2002, we were notified that Barr Laboratories, Inc. had submitted an ANDA with the U.S. FDA seeking permission to market a generic version of Evista several years prior to the expiration of our U.S. patents covering the product, alleging that the patents are invalid or not infringed. In November 2002, we filed suit against Barr in the U.S. District Court for the Southern District of Indiana seeking a ruling that Barr's challenges to our patents claiming the method of use and pharmaceutical form (expiring from 2012 to 2017) are without merit. In June 2003, Barr added a challenge to one of our additional patents (expiring in 2017) claiming a component in the pharmaceutical form of Evista. That patent has been added to the lawsuit. The suit is in discovery with a trial date currently proposed for August 2005. While we believe that Barr's claims are without merit and expect to prevail, it is not

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possible to predict or determine the outcome of the litigation. Therefore, we can provide no assurance that we will prevail. An unfavorable outcome could have a material adverse impact on our consolidated results of operations, liquidity, and financial position.

In October 2002, Pfizer Inc. filed a lawsuit in the United States District Court in Delaware against us, Lilly ICOS LLC, and ICOS Corporation alleging that the proposed marketing of Cialis for erectile dysfunction would infringe its newly issued method-of-use patent. In September 2003, the U.S. Patent and Trademark Office, on its own initiative, ordered that Pfizer's patent be reexamined. The Delaware suit has been stayed pending the outcome of the reexamination. Previously, Pfizer's corresponding European method-of-use patent was held invalid in the first stage of an opposition proceeding in the European Patent Office. Pfizer is now appealing that decision to the Technical Board of Appeal of the European Patent Office. A hearing is expected in the second half of 2004. The U.K. Court of Appeal has previously held the U.K. counterpart to this patent invalid. Litigation relating to the corresponding patent is pending in Australia, Brazil, Canada, Mexico, New Zealand, and South Africa. We intend to vigorously defend this litigation and expect to prevail. However, it is not possible to predict or determine the outcome of this litigation and therefore we can provide no assurance that we will prevail.

**Product Liability Litigation**

We are currently a defendant in a variety of product liability litigation lawsuits in the United States involving primarily diethylstilbestrol ("DES") and thimerosal.

In approximately 115 U.S. actions, including several with multiple claimants, plaintiffs seek to recover damages on behalf of children or grandchildren of women who were prescribed DES during pregnancy.

We have been named as a defendant in approximately 315 actions in the U.S., involving approximately 820 claimants, brought in various state courts and federal district courts on behalf of children with autism or other neurological disorders who received childhood vaccines (manufactured by other companies) that contained thimerosal, a generic preservative used in certain vaccines in the U.S. from the 1930's until approximately 2000. We discovered and developed thimerosal in the 1920's. We have been named in the suits even though we discontinued manufacturing the raw material in 1974 and discontinued selling it in the United States to vaccine manufacturers in 1992. The lawsuits typically name the vaccine manufacturers as well as Lilly and other distributors of thimerosal, and allege that the children's exposure to thimerosal-containing vaccines caused their autism or other neurological disorders. We strongly deny any liability in these cases. There is no credible scientific evidence establishing a causal relationship between thimerosal-containing vaccines and autism or other neurological disorders. In addition, we believe the cases should not be prosecuted in the courts in which they have been brought because the underlying claims are subject to the National Childhood Vaccine Injury Act of 1986. Implemented in 1988, the Act established a mandatory, federally administered no-fault claims process for individuals who allege that they were harmed by the administration of childhood vaccines. Under the Act, claims must first be brought before the U.S. Court of Claims for an award determination under the compensation guidelines established pursuant to the Act. Claimants who are unsatisfied with their awards under the Act may reject the award and seek traditional judicial remedies.

We have been named in approximately 15 product liability cases in the United States involving plaintiffs claiming a variety of injuries from the administration of Zyprexa. Most of the cases allege that the product caused or contributed to diabetes or high blood glucose levels. We are vigorously defending these suits. Our request that the Zyprexa matters pending in federal courts be consolidated in a Multidistrict Litigation (MDL) before one federal judge for pre-trial purposes will be considered on March 23, 2004.

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**Other Matters**

In July 2002, we received a grand jury subpoena for documents from the Office of Consumer Litigation, Department of Justice, related to our marketing and promotional practices and physician communications with respect to Evista. We received a second subpoena seeking additional documents in July 2003. We continue to cooperate with the government and have provided a broad range of information concerning our U.S. marketing and promotional practices, including documents relating to communications with physicians and the remuneration of physician consultants and advisers. We continue to review and enhance policies and procedures designed to assure that our marketing and promotional practices and physician communications comply with promotional laws and regulations. In recent months, several pharmaceutical companies have received subpoenas from government agencies with respect to a variety of products, including a number of neuroscience products. It is possible that other Lilly products, including Zyprexa, could become subject to investigation. It is possible that the outcome of the above matters could include criminal charges and fines and/or civil penalties. We cannot predict or determine the outcome of the above matters or reasonably estimate the amount or range of amounts of any fines or penalties that might result from an adverse outcome. It is possible, however, that an adverse outcome could have a material adverse impact on our consolidated financial position, liquidity and results of operations.

In August 2003, we received notice that the staff of the SEC is conducting an investigation into the compliance by Polish subsidiaries of certain pharmaceutical companies, including Lilly, with the U.S. Foreign Corrupt Practices Act of 1977. The staff has issued subpoenas requesting production of documents related to the investigation. We are cooperating with the SEC in responding to the investigation.

In March 1996, the U.S. Federal Trade Commission (FTC) commenced a non-public antitrust investigation focusing on the pharmaceutical industry practice of providing discounts or rebates to managed-care organizations and certain other purchasers. We are cooperating with the investigation and have responded to two subpoenas from the FTC requesting production of certain documents and other discovery responses. We have received no additional requests for documents or information for several years. We believe that all of our actions have been lawful and proper.

In March 2001, we received a subpoena, issued at the request of the Commonwealth's attorney for the Commonwealth of Massachusetts, for production of documents related to pricing and Medicaid reimbursement of our products in Massachusetts. We are not the only pharmaceutical company to receive such a request. We are cooperating with the inquiry and we believe that all of our practices have been lawful and proper.

In 2003, three counties in New York (Suffolk, Rockland, and Westchester) sued Lilly and many other pharmaceutical manufacturers, claiming in general that as a result of alleged improprieties by the manufacturers in the calculation and reporting of average wholesale prices for purposes of Medicaid reimbursement, the counties overpaid their portion of the cost of pharmaceuticals. The suits seek monetary and other relief, including civil penalties and treble damages. The three county suits have been transferred to the U.S. District Court for the District of Massachusetts for pretrial proceedings (along with several other suits to which Lilly is not a party). The Suffolk County case is now the subject of a pending motion to dismiss, and the Rockland and Westchester cases are stayed pending the resolution of that motion. While we are vigorously defending these cases, given their early procedural stage, we cannot predict or determine the outcome of this litigation, and therefore we can provide no assurance that we will prevail.

We are also a defendant in other litigation and investigations, including product liability and patent suits, of a character we regard as normal to our business.

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While it is not possible to predict or determine the outcome of the legal actions and investigations described above, we believe that except as otherwise specifically noted above, the resolution of all such matters will not have a material adverse effect on our consolidated financial position or liquidity but could possibly be material to our consolidated results of operations in any one accounting period.

**Item 4. Submission of Matters to a Vote of Security Holders**

During the fourth quarter of 2003, no matters were submitted to a vote of security holders.

**Part II**

**Item 5. Market For the Company's Common Stock and Related Stockholder Matters**

You can find information relating to the principal market for our common stock and related stockholder matters in our 2003 Annual Report under "Selected Quarterly Data (unaudited)," at page 25 (page 18 of Exhibit 13), and "Selected Financial Data (unaudited)," at page 26 (page 19 of Exhibit 13). That information is incorporated in this Report by reference.

**Item 6. Selected Financial Data**

You can find selected financial data for each of our five most recent fiscal years in our 2003 Annual Report under "Selected Financial Data (unaudited)," at page 26 (page 19 of Exhibit 13). That information is incorporated in this report by reference.

**Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition**

You can find management's discussion and analysis of results of operations and financial condition in the following portions of our 2003 Annual Report (found at pages 1-5, 7, and 9-14 of Exhibit 13):

"Review of Operations—Executive Overview" (pages 8-10)
"Review of Operations—Operating Results—2003" (pages 10-12)
"Review of Operations—Operating Results—2002" (pages 12 and 14)
"Review of Operations—Financial Condition" (pages 16-18)
"Review of Operations—Application of Critical Accounting Policies" (pages 18-20)
"Review of Operations—Financial Expectations for 2004" (page 20)
"Review of Operations—Legal and Environmental Matters" (pages 20-21)
"Review of Operations—Private Securities Litigation Reform Act of 1995 – A Caution Concerning Forward-Looking Statements" (page 21)

The information referred to above is incorporated in this report by reference.